



LifeStand "Vivre-Debout"
Rond-point de Rosarge
40, rue Palverne
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EXHIBIT #1

K 042596

JAN 26 2005

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

**Lifestand
Rond-point de Rosarge
40, rue Palverne
F 01700 LES ECHETS-FRANCE**

Date Summary Prepared: September 06th, 2004

2. **Name of the Device:**

LSA Helium

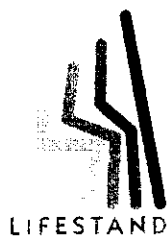
3. **Common or Usual Name:**

manually propelled standup wheelchair

4. **Device Description:**

The LSA Helium is a manually propelled standup wheelchair. It is propelled and steered by varying the speed of the two back wheels. Front castors support the front of the chair and allow indirect steering through the turning back wheels. A gas-spring-system supports the customer in putting the seat manually into a seating or standing position.

Maximum end-user weight :	100 kg
Wheelchair width :	36/38/40/42/44/46cm
Wheelchair seat depth :	40 to 50 every 2 cm
Frame :	Rigid, in magnesium, epoxy paint
Seat :	Depth adjustable, with sore proof cushion
Backrest :	Inclinable. Folds down for transport
Upholstery :	Polyester fireproof material (M4), washable
Foot-rests :	Height adjustable
Front wheels :	Ø 125mm x 29mm, solid
Rear wheels :	Ø 600mm x 25mm, 1000kPa
Brakes :	Hand, by pushing
Propulsion :	Manual
Elevation :	Manual assisted by gas-powered springs, adjustable according to the user's weight.
Rear stabilization :	Anti-tip wheels (optional).
Idle weight :	17,9kg



5. **Intended Use:**
The LSA Helium offers manually operated seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.
6. **Comparison to Predicate Devices:**
The LSA Helium is substantially equivalent to the standup wheelchair LAE (LEVO Active Easy) by LEVO, K971873
7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**
To approve the performance of the LSA Helium, tests according to current applicable standards were performed at test-laboratories of European notified bodies:

EN 12182: 1999	Technical aids for disabled persons. General requirements and test methods
EN 12183: 1999	Manually propelled wheelchairs. Requirements and test methods
ISO 7176-1: 1999	Wheelchairs. Determination of static stability
ISO 7176-3: 1988	Wheelchairs. Determination of effectiveness of brakes
ISO 7176-5: 1986	Wheelchair tests. Methods for determination of overall dimensions, mass and turning space
ISO 7176-7: 1998	Measurement of seating and wheel dimension
ISO 7176-8: 1998	Wheelchairs. Requirements and test methods for static, impact and fatigue strengths
ISO 7176-15: 1996	Wheelchairs. Requirements for information disclosure, documentation and labeling
ISO 10993-5: 1999	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
NFP 92503:	flammability
NFP 92505:	flammability
ISO 6941: 2003	Textile fabrics. Burning behavior. Measurement of flame spread properties of vertically oriented specimens
8. **Discussion of Clinical Tests Performed:**
Clinical tests were not performed
9. **Conclusions:**
Lifestand believes that the LSA Helium is substantially equivalent to the predicate and is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 26 2005

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

Ms. Stephanie D. Bankston
Official Correspondent for Lifestand
Lifestand
10925 Beamer #290
Houston, Texas 77089

Re: K042596
Trade/Device Name: LSA Helium
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: II
Product Code: IPL
Dated: January 11, 2005
Received: January 14, 2005

Dear: Ms. Stephanie D. Bankston

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

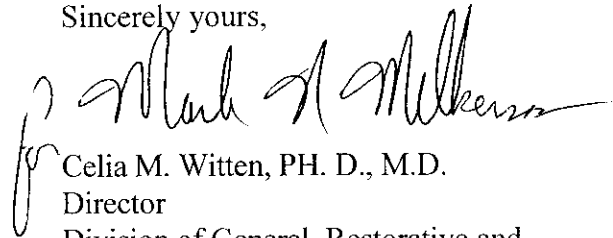
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Stephanie D. Bankston

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, PH. D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K042596

Device Name: LSA Helium

Indications For Use:

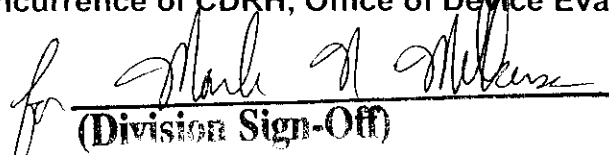
The LSA Helium offers seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR Over-The Counter Use _____
(21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K042596